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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,375	07/07/2000	ANTHONY DAVID ORMEROD	ABLE-0014	4066
7590 08/19/2004 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER 1300 I STREET N.W. WASHINGTON, DC 20005-3315			EXAMINER GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/530,375

**Applicant(s)**

ORMEROD ET AL.

**Examiner**

Konata M. George

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on RCE filed May 26, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24,25,28-31 and 37-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-51 is/are allowed.
- 6) ☒ Claim(s) 24,25,28,29,32,36-39,52-54 and 61-63 is/are rejected.
- 7) ☒ Claim(s) 55-60 and 64-66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 24, 25, 28-31 and 37-66 are pending in this application.

#### ***Request for Continued Examination (RCE)***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2004 has been entered.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on May 26, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Action Summary***

3. Examiner acknowledges the addition of claim 52-66.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 24, 25, 28, 29, 32 and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Francoeur et al. (EP 0 435 436 A2).

Francoeur discloses a topical administration of a pharmaceutical agent, an aqueous solvent and a dermal penetration enhancer (page 2, lines 37-46). Page 2, lines 47-51 describe preferred dermal penetration enhancers, where the most preferred is oleic acid. Page 3, lines 43-44 teach the use of azithromycin as an active agent in the composition.

5. Claims 24, 25, 28, 29, 32, 37, 38 and 61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pittrof et al. (US Pat. No. 5,376,646).

Pittrof teaches a topical preparation containing cholanic acid and a lipid. The composition may also contain active substances of ingredients which such as immunosuppressives such as FK 506 and antibiotics (col. 1, lines 48-68). For the preparation of creams or salves paraffins, waxes, and fats can be incorporated (col. 2, lines 41-50). Adjuvants and additives may be incorporated such as penetration-

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enhancers i.e. oleic acid and also solvents may be incorporated i.e. ethanol, DMSO or organic amides (col. 2, lines 51-63).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 24, 25, 28-32, 36-39 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pittrof et al. (US Pat. No. 5,376,646) in view of San-Doz Ltd. (WO 96/13249).

Pittrof teaches a topical preparation containing cholanic acid and a lipid. The composition may also contain active substances of ingredients which such as immunosuppressives such as FK 506 and antibiotics (col. 1, lines 48-68). For the preparation of creams or salves paraffins, waxes, and fats can be incorporated (col. 2, lines 41-50). Adjuvants and additives may be incorporated such as penetration-enhancers i.e. oleic acid and also solvents may be incorporated i.e. ethanol, DMSO or organic amides (col. 2, lines 51-63). The prior art does not teach the topical used to treat the claimed dermatological conditions.

San-Doz Ltd. discloses a topical composition in the form of an emulsion that comprises the compound FK506. The composition is used to treat inflammatory and

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hyperproliferative skin diseases such as psoriasis, eczematous dermatitis's, lupus erythematosus, alopecia areata, etc. (page 12, lines 15-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of San-Doz Ltd. to administer the composition of Pittrof to treat the claimed dermatological conditions, because it is taught in San-Doz (page 12, lines 15-20) that FK 506 is used inflammatory and hyperproliferative skin diseases. The expected result would be a topical formulation for treating dermatological conditions comprising an immunosuppressive macrolide and a permeation enhancer.

### ***Response to Arguments***

7. Applicant's arguments filed May 26, 2004 have been fully considered but they are not persuasive.

Applicants argue that the prior art of Francoeur does not teach the drug composition producing a "minimal systemic effect". Applicant recites page 2, lines 11-14 stating the "the drug is 'phoresed' from the solution across the dermal barrier and into the local tissue (to produce high local tissue levels of the drug), or given enough time and other appropriate conditions, into the blood stream, whereby the drug is delivered systemically to more remote site(s) of action." It is the position of the examiner that Francoeur discloses the claimed invention. Francoeur is directed toward a topical administration of drugs by iontophoresis. Although it is disclosed that the drug can be delivered systemically too more remote site(s) if action, it is not the basis of the invention, that is a situation-by-situation basis. Page 3, lines 4-7 teaches two situations

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(1) treating localized pain or inflammation, or localized bacterial or fungal infection) or (2) systemic delivery to remote locations. Therefore, it is the position of the examiner that since the prior art teaches that localized conditions can be treated with the invention then it does produce a “minimal systemic effect”.

Applicant argues that Pittrof does not disclose an example employing any of the claimed antibiotic or immunosuppressive macrolides or that the compositions produce a “minimal systemic effect”. It is the position of the examiner that the prior art reference of Pittrof discloses the claimed invention. Example 9, column 6, lines 22-39 teaches a composition containing Cyclosporin A as an active agent. Column 1, lines 58-59 teach that Cyclosporin A and FK 506 are compounds of the same class, immunosuppressives. Therefore, it is the position of the examiner that since they belong to the same class that they can be used interchangeably. With respect to the prior art failing to produce a “minimal systemic effect”, it is the position of the examiner that the prior does meet this limitation. Claim 1 of the prior art reads “A method of facilitating penetration and distribution of a pharmaceutically active substance into the skin of a host...” With this being said it is obvious that the composition is being administered to the skin and not “systemically”.

***Allowable Subject Matter***

8. Claims 40-51 are allowed.


9. Claims 55-60 and 64-66 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

  
Konata M. George  
Patent Examiner  
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